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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/848,164 05/03/01 RHODE

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EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

10/23/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/848,164

Applicant(s)
Rhode et al.

Examiner
D Cloux, Amy

Art Unit
1644



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 3, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 29-31, 35-37, 43-48, and 52-87 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 29-31, 35-37, 43-48, and 52-87 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

DETAILED ACTION

1. Applicant's preliminary amendment, mailed 5-3-01 in Paper No. 3, is acknowledged.
2. However, the newly added claims presented in Applicant's preliminary amendment, mailed 5-3-01, are misnumbered. Applicant has directed said claims to be numbered as 52-86. However, claim 52 was presented in the case as originally filed. Therefore, the newly added claims have been renumbered in accordance with rule 1.126 as claims 53-87.
3. A restriction is required under 35 USC 121 between one of the following groups:
 - I. Claims 29-31, drawn a method of suppressing an immune response in a mammal comprising administering to the mammal an effective amount of a DNA sequence comprising the DNA construct of now canceled claim 28, classified in class 536, subclass 23.6,
 - II. Claims 35-37, drawn a method of inducing an immune response in a mammal comprising administering to the mammal an effective amount of a DNA sequence comprising the DNA construct of now canceled claim 34, classified in class 536, subclass 23.6,
 - III. Claims 43-48, drawn a method of suppressing an immune response in a mammal comprising administering to the mammal an effective amount of the cells of now canceled claim 42, classified in class 424, subclass 93.2,
 - IV. Claim 52, drawn to a method of inducing T cells comprising contacting the T cells with the MHC complex of now canceled claim 7, classified in class 424, subclass 184.1,
 - V. Claims 53-55, 57-63, 66-69, and 71-76, drawn to a single chain Class II MHC molecule, classified in class 530, subclass 350,
 - VI. Claims 56, 64-65, 70, 77-78 drawn to a DNA construct encoding a single chain Class II MHC molecule, classified in class 536, subclass 23.6, and class 435, subclasses 69.1, 91.1, 320.1, and 252.3,

VII. Claims 79-81, drawn to a method for identifying presenting peptides that bind a Class II MHC molecule, classified in Class 435, subclass 7.21,

VIII. Claims 82-87, drawn to a method of inducing an immune response in a mammal comprising administering to the mammal an effective amount of a single chain class II molecule, classified in class 424, subclass 184.1.

4. The inventions listed as Groups I-VI are distinct for the following reasons:

5. Groups V and VI are unique products. They differ with respect to their structures and physicochemical properties, the former group encompassing polypeptides while the latter encompasses polynucleotides, and are therefore patentably distinct.

6. Groups I-IV and VII-VIII are unique methods. Groups I/III, Groups II/VIII, Group IV and Group VII all have distinct endpoints and process steps. Group I and Group III have the same endpoint but differ with respect to ingredients. Group II and Group VIII have the same endpoint but differ with respect to ingredients. Therefore, Groups I-IV and VII-VIII are patentably distinct each from the other.

7. Group V and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the single chain class II molecule can be used as an immunogen in a process of making monoclonal antibodies.

8. Group V and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the single chain class II molecule, can be used in a process of affinity purification of Class II antibodies.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
October 19, 2001

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644